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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,756	12/21/2001	Terry L. Thomas	8383zyxwvut	6460
7590 01/13/2005 Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530			EXAMINER MCELWAIN, ELIZABETH F	
			ART UNIT 1638	PAPER NUMBER
DATE MAILED: 01/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,756

Applicant(s)

THOMAS, TERRY L.

Examiner

Elizabeth F. McElwain

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-59 is/are pending in the application.
- 4a) Of the above claim(s) 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 48 and 51-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed October 18, 2004 has been entered.

Claims 47, 48, 51, 54 and 55 are currently amended.

Claims 56-59 are newly submitted.

Election/Restrictions

This application contains claims 49 and 50 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

New claims 58 and 59 are objected to for reciting "An isolated", instead of "The isolated" at the start of the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim 59 recites fragments of SEQ ID NO: 5. However, there was no support for the particular residues that are recited in the specification as originally filed.

Claims 47, 48 and 51-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the last office action.

4. Applicant's arguments filed October 18, 2004 have been fully considered but they are not persuasive. Applicant asserts that a written description is provided in the specification given that several gene sequences are disclosed and a gain of function assay is described. In addition, applicant argues that the specification teaches specific structural motifs, the Lipid Box, the Metal Box 1 and the Metal Box 2 in the Borage delta-6 desaturase. The specification also teaches three identical "histidine rich" motifs in the Evening Primrose delta-6 desaturase, which the specification states are common structural features present in all plant delta-6 desaturases. The specification also states that other delta-6 desaturases can be obtained by hybridization to the Borage or Evening Primrose delta-desaturase DNA.

5. The Examiner maintains that the specific structural features that are required for delta-6 desaturase activity, and thereby define the genus claimed, are not described. Table 3 provides

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a listing of sequence boxes from different delta-6 desaturase genes compared to each other.

However, these alignments make clear that there are many differences between the sequences in these stated boxes. Therefore, it is unclear which sequences are required for the delta-6 desaturase activity.

6. Claims 47, 48 and 51-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid sequences that encode a delta-6 desaturase from the plant species: evening primrose and borage, and from *Synechocystis* and cyanobacteria, does not reasonably provide enablement for any delta-6 desaturase from any species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action.

7. Applicant's arguments filed October 18, 2004 have been fully considered but they are not persuasive. Applicant asserts that several gene sequences are disclosed and a gain of function assay is described. In addition, applicant argues that the specification teaches specific structural motifs, the Lipid Box, the Metal Box 1 and the Metal Box 2 in the Borage delta-6 desaturase. Applicant also argues that the specification also teaches three identical "histidine rich" motifs in the Evening Primrose delta-6 desaturase, which the specification states are common structural features present in all plant delta-6 desaturases. In addition, applicant asserts that the specification also states that other delta-6 desaturases can be obtained by hybridization to the Borage or Evening Primrose delta-desaturase DNA. Therefore, applicant argues that it would not require undue experimentation to identify nucleic acids encoding delta-

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6 desaturases. In addition, applicant has submitted several publications: Sterling et al, Girke et al, and Garcia-Maroto each teach using primers derived from sequence fragments encoding "histidine rich" domains.

8. The Examiner maintains that it would require undue experimentation to make and/or use the invention as broadly claimed for the reasons of record in the last office action and the primers used in the post-filing date references submitted are not specifically set forth in the specification.

The claims are deemed free of the prior art given that a delta-6 fatty acid desaturase coding sequence was not taught or suggested by the prior art of record.

No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.

Primary Examiner

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EFM